

Conclusion

Directive 98/79/EC on in vitro diagnostic medical devices—which includes genetic tests and self tests—is mainly concerned with the safety and performance of the product and protection of the health of those working with it. It is less concerned with the manner in which genetic testing services (including test interpretation and counselling are promoted and carried out.²⁰ The directive states, however, that manufacturers who place tests and testing devices on the market shall notify the competent authorities of the member states²¹ of the product, its quality and performance. This makes it possible for national overseeing bodies to monitor the new developments regarding predictive genetic testing. The interrelation and interaction of value judgments with respect to the burden of a genetic condition and its treatment for individual, family, health care or society, plus the need to balance the benefits and dangers for the different interested parties, together with the advent of commercial genetic testing services, justifies the establishment of a national overseeing body with the task of proposing and enforcing regulations acceptable to all interested parties.

Acknowledgements

I am grateful to the Commission of the European Communities for funding the EUROSCREEN II project of which this paper forms a part.

Rogeer Hoedemaekers is Research Fellow in the Department of Ethics, Philosophy and History of Medicine, School of Medical Sciences, KUN Nijmegen, the Netherlands.

References and notes

- 1 Council of Europe. *Explanatory report to the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine*. Strasbourg: Directorate of Legal Affairs (DIR/JUR (97) 1, 1997.
- 2 Focus is on *predictive* genetic tests in (apparently) healthy persons, not on *diagnostic* genetic testing of patients for better prognosis, treatment or other forms of intervention.
- 3 Wilfond B, Nolan K. National policy development for the clinical application of genetic diagnostic technologies. *Journal of the American Medical Association* 1993;270:2948-54.
- 4 Advisory Committee on Genetic testing. *Code of practice and guidance on human genetic testing services supplied direct to the public*. London: Health Departments of the United Kingdom, 1997.
- 5 Hoedemaekers R, ten Have H. The concept of abnormality in medical genetics. *Theoretical Medicine and Bioethics* 1999;20: 537-61.
- 6 Hoedemaekers R, ten Have H. Geneticisation: the Cyprus paradigm. *Journal of Medicine and Philosophy* 1998;23:274-87.
- 7 Nordenfelt L. *On the nature of health. An action-theoretic approach*. Dordrecht, Boston, London: Kluwer Academic Publishing, 1995.
- 8 Hoedemaekers R. Genetic screening and testing: a moral map. In: Chadwick R, Shickle D, ten Have H, Wiesing U, eds. *The ethics of genetic screening*. Dordrecht, Boston, London: Kluwer Academic Publishing, 1999:207-30.
- 9 For example, Andrews L, Fullarton J, Koltzmann N, Motulsky A. *Assessing genetic risks, implications for health and social policy*. Washington DC: National Academy Press, 1994; Nuffield Council on Bioethics. *Genetic screening: ethical issues*. London: Nuffield Council on Bioethics, 1993.
- 10 Health Council of the Netherlands (Gezondheidsraad). *Erfelijkheid: wetenschap en maatschappij*. Den Haag: Gezondheidsraad, 1989.
- 11 Health Council of the Netherlands (Gezondheidsraad). *Commissie Screening Erfelijke en Aangeboren Aandoeningen. Genetische screening*, Den Haag: Gezondheidsraad, 1994.
- 12 See reference 9: Andrews L, et al, 1994.
- 13 Working Party of the Clinical Genetics Society (UK). The genetic testing of children. *Journal of Medical Genetics* 1994;31: 785-97.
- 14 Holtzman N, Watson M. *Promoting safe and effective genetic testing in the United States: final report of the Task Force on Genetic testing*. Baltimore: Johns Hopkins University Press, 1997.
- 15 Harper P. 'Over the counter' genetic testing: lessons from cystic fibrosis carrier screening. In: Harper P, Clarke A, eds. *Genetics, society and clinical practice*. Oxford: Bios Scientific Publishers, 1997:67-73. Bull S. Mail order gene testing. *Bulletin of Medical Ethics* 1996; February: 20-1.
- 16 Lenaghan J. *Brave new NHS? The impact of the new genetics on the health service*. London: Institute for Public Policy Research, 1998.
- 17 Post S, Whitehouse P, Binstock R, Bird T, Eckert S, Farrer L, et al. The clinical introduction of genetic testing for Alzheimer Disease (consensus statement). *Journal of the American Medical Association* 1997;277:832-6.
- 18 Fost W. Ethical implications of screening asymptomatic individuals. *FASEB Journal* 1992;6:2816.
- 19 In the UK, most of these groups are represented on the Advisory Committee on Genetic Testing.
- 20 Directive of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices. *Official Journal of the European Communities* 1998 Dec 7: L331/1-L331/37.
- 21 See reference 20: article 10.

News and notes

Journal of Medical Ethics - <http://www.jmedethics.com>

Visitors to the world wide web can now access the *Journal of Medical Ethics* either through the BMJ Publishing Group's home page (<http://www.bmjpg.com>) or directly by using its individual URL (<http://www.jmedethics.com>). There they will find the following:

- Current contents list for the journal
- Contents lists of previous issues
- Members of the editorial board
- Subscribers' information
- Instructions for authors
- Details of reprint services.

A hotlink gives access to:

- BMJ Publishing Group home page
- British Medical Association website
- Online books catalogue
- BMJ Publishing Group books.

The web site is at a preliminary stage and there are plans to develop it into a more sophisticated site. Suggestions from visitors about features they would like to see are welcomed. They can be left via the opening page of the BMJ Publishing Group site or, alternatively, via the journal page, through "about this site".